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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	**PAPER NUMBER**
1636	12

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/736,268	CHAPMAN, KAREN B.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,26-32 and 36-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,26-32 and 36-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Receipt is acknowledged of a reply, filed February 13, 2003 as Paper No. 11, to the previous Office Action. Amendments were made to the claims. Specifically, claims 17-25 and 33-35 were cancelled and new claims 36-53 were added.

Claims 1-16, 26-32 and 36-53 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 9, mailed September 13, 2002, that is not addressed in this action has been withdrawn.

Because this Office Action contains only rejections that are necessitated by amendment or that are maintained for reasons set forth in the previous Office Action, the action is made FINAL.

Claim Rejections - 35 USC § 112

Claims 1-16, 26-32 and 36-53 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the amendments to the claims reciting, "wherein said introduction of cytoplasm does not result in the production of an embryo" do not have literal support in the instant specification. **This is a new rejection necessitated by amendment.**

Applicant has amended the instant claims to contain the new limitation recited above in an attempt to overcome the art rejections presented in the previous Office Action, as indicated on page 7 of the reply to said Office Action. Specifically, the reply states, "Independent claims 1

and 26 are amended to specify methods wherein the introduction of cytoplasm does not result in production of an embryo. This feature of the invention is taught in the specification (page 4, lines 18-20), and clearly distinguishes the claimed invention from the methods of the prior art." The passage on page 4, lines 18-20 of the instant specification states, "However, it would be beneficial if methods could be developed for converting differentiated cells to embryonic cell types, without the need for cloning, and the production of embryos, especially given their potential for use in nuclear transfer and for producing different differentiated cell types for therapeutic use." It is important to note that this statement does not indicate that embryos are not produced, rather indicating that embryos are produced along with other embryonic cell types. Since there is no indication in the specification for the limitation wherein an embryo is not produced, the amendment to the claim does not have literal support in the specification and therefore represents new matter. Furthermore, all of the claims pending in the instant application depend from a claim reciting this limitation. As a result, all of the claims as amended stand rejected under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-8, 14-16, 26, 28, 29, 32, 36-39 and 42-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Robl, et al. (US Patent Publication 2001/0012513 A1). **This rejection is both maintained for the reasons set forth in the previous Office Action, and necessitated by amendment as applied to the newly added claims 36-39 and 42-45.**

Support for the rejection of new claim 38, which is an independent claim reciting the new limitation that the de-differentiated cell produced by contacting a more differentiated cell with the cytoplasm of a less differentiated cell, can be found on page 3, paragraph [0033]. Specifically, the paragraph states that the stem-cells produced can then be used in transplantation therapy by using isogenic or synegenic cells, tissues and organs produced from the produced from said stem-cells. This necessarily requires that the produced stem-cells be further differentiated in order to produce an organ or tissue, considering that organs and tissues are differentiated tissues, therefore Robl also anticipates this aspect of the invention. As the remaining limitations of the claims have been addressed in the previous Office Action, their reiteration here would be redundant, as they would apply equally to cells that are produced and then differentiated and cells that are produced without further differentiated.

Response to Arguments Concerning Claim Rejections Under 35 USC § 102

Applicant's arguments filed February 13, 2003 have been fully considered but they are not persuasive. Specifically:

1. Applicant contends that the amendment of the claims to indicate, "wherein said introduction of cytoplasm does not result in the production of an embryo" distinguishes the claimed invention from the methods of the prior art, specifically Robl in this instance.

2. Applicant contends that none of the references teaches a method of producing de-differentiated cells, specifically Robl in this instance.

Applicant's arguments are not convincing for the following reasons:

1. Notwithstanding the lack of a written description for the amended claims, Robl clearly indicates the production of cells that are not necessarily embryos; specifically there is a description for the production of embryonic stem cells (see for example page 4, paragraphs [0050-0055]). This procedure involves contacting the cytoplasm of a less differentiated cell (in this case an enucleated oocyte), and contacting a human or animal cell with said cytoplasm of the oocyte in some embodiments (see specifically page 4, paragraph [0054]). This de-differentiated cell is then cultured to obtain embryonic or stem-like cells which are not necessarily embryos. Therefore, Robl still anticipates the claimed methods in view of applicant's argument that the reference only teaches the production of embryos.

2. Applicant's contention that Robl does not teach the de-differentiation of a cell is baseless. Robl clearly indicates on page 4, paragraph [0057] that a variety of differentiated cells can be used in their method, including all somatic cells (see last sentence in the paragraph). In order for these cells to become stem cells, they must necessarily de-differentiate from their somatic nature. Therefore, Robl also teaches the de-differentiation of a cell which is contacted with the cytoplasm of a less differentiated cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 9-13, 27, 30, 40, 41 and 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robl, et al., in view of Thomson (*Science* **282**:1145-1147, 1998), in further view of Greider, et al. (WO 97/35967). **This rejection is both maintained for the reasons set forth in the previous Office Action, and necessitated by amendment as applied to the newly added claims 40, 41 and 46-53.**

As indicated above under the 35 USC 102 rejections, support for the rejection of newly added claim 38 can be found on page 3, paragraph [0033] of Robl. Since the remaining limitations of the claims have been addressed in the previous Office Action, their reiteration here would be redundant, as they would apply equally to cells that are produced and then differentiated and cells that are produced without further differentiated. This also applies to the limitations recited in the newly added claims 40, 41 and 46-53, which would be as applicable to stem cells that will undergo differentiation as they are to stem-cells that do not necessarily undergo differentiation. Therefore, the application of Robl in view of Thomson and in further view of Greider as applied in the previous Office Action towards the rejection of claims 3, 4, 9-13, 27 and 30, is now applied for the same reasons to newly added claims 40, 41 and 46-53.

Response to Arguments Concerning Claim Rejections Under 35 USC § 103

Applicant's arguments filed February 13, 2003 have been fully considered but they are not persuasive. Specifically, applicant contends that the amendments and arguments made with respect to the rejections under 35 USC 102 are sufficient to overcome the rejections under 35

USC 103, simply by overcoming the 35 USC 102 rejections. This is not persuasive because neither the arguments nor the amendments are sufficient to overcome the rejections under 35 USC 102 as indicated above, and therefore are insufficient to overcome the rejections under 35 USC 103 for the same reasons. As a result, the rejections under 35 USC 103 are maintained.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
April 21, 2003

DAVID GUZO
PRIMARY EXAMINER